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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,338	10/23/2003	Terri L. Butler	BP. 028 US2	8488

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KATHLEEN R. TERRY
2417 COMO AVENUE
ST. PAUL, MN 55108

EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,338	BUTLER ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/30/05, 10/23/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: in applicant's claim to priority, in the 1st paragraph of the specification, applicants have not clearly stated the nature of the relationship between the instant application and those from which it depends. Stating that the instant application is "related to" provisional application 60/221,526, for example, will not substitute for stating that the application claims priority to the provisional application. Appropriate correction is required.

Moreover, it is noted that the applications to which the instant application claims priority to are not seen to provide adequate support under 35 USC 112 1st paragraph for claims 1-6 of the instant application. Specifically, applicants are not seen to have support for the closed language which they use, i.e. "consisting of". As such, the examiner is treating this case as a CIP case, not a CON case, and applicants are only afforded a priority date of the filing of the instant application, 10/23/2003.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: applicants are claiming methods and compositions "consisting of" the various agents, but do not have support for the use of the closed claim language in the specification.

Additionally, applicants are reminded to use the proper status identifiers for the claims in all subsequent communications. It is noted that claims 1-6 are pending and claims 7-17 are canceled, as claims 7-17 were filed with the original disclosure.

Information Disclosure Statement

It Is noted that the examiner has lined through the references which were cited on the IDS filed on 10/23/2003 due the fact that the references were listed on a PTO-892 form, not a 1449 form, and were indicated as being in application number 09/917,292. The examiner has placed all of the references on a PTO-892 form which identifies the instant application instead of a divergent application to provide clarity and ensure the references applicants whishes to be considered are considered.

Claim Objections

Claim 5 is objected to because of the following informalities: applicants have misspelled the word "and" as "ad" at the end of line 3 of the claim ("Vitamin B12 **ad** six milligrams of Vitamin B6"). Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,218,366. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods of treating vascular conditions using the same therapy, i.e. with ribose or ribose and a vasodilator. It is noted that the instant claims are drawn to methods of improving cardiovascular function in a subject with congestive heart failure and the '366 patent is drawn to methods of increasing the tolerance of a mammal to hypoxia. It is noted that hypoxia is seen to be a precipitating factor of congestive heart failure, as evidenced by the attached "How Congestive Heart Failure Works", and as such, it is believed that a skilled artisan would find it obvious to practice the method of the '366 patent in a patient with congestive heart failure (CHF) as hypoxia is known to occur in vascular disease and known to be a precipitating factor associated with CHF. Claim 10 of the '366 patent further states that hypoxia is due to cardiovascular disease, further overlapping the instant claims of treating CHF with the '366 patent.

Claims 1-3 and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 11/118,613. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to treating vascular conditions using the same therapy. It is noted that the instant application is drawn to improving cardiovascular function in a subject with congestive heart failure and the '613 application is drawn to methods of improving ventilatory efficiency in a subject having reduced ventilatory efficiency, however, CHF is known to occur when the flow of blood from the heart decreases, or fluid backs up in the failing ventricle, or both. and thus increasing the blood flow from the heart would also be seen to improve ventilatory efficiency, as ventilatory efficiency is the rate at which CO_2 is removed from the body, thus dependent on the output rate of the heart. Thus, a subject having CHF, as in the instant application, is seen to be a subject that has reduced ventilatory efficiency as in the '613 patent. One of skill in the art would find it obvious that these applications are substantially overlapping in the subject matter that they are claiming.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 recite the limitation of methods of compositions "consisting of" the various agents. There is insufficient antecedent basis for this limitation in the claims as the specification does not provide any guidance for the closed language used (consisting of). It is noted that applicants did not make any compositions with solely the claimed agents as set forth in claims 4-5, nor provide singular therapy in any of the methods tested. The specification should provide proper antecedent support for that which is claimed. Per the MPEP:

> New claims and amendments to the claims already in the application should be scrutinized not only for new matter but also for new terminology. While an applicant is not limited to the nomenclature used in the application as filed, *he or she should make appropriate amendment of the specification* whenever this nomenclature is departed from by amendment of the claims *so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims*. This is necessary in order to insure certainty in construing the claims in the light of the specification, Ex parte Kotler, 1901 C.D. 62, 95 O.G. 2684 (Comm'r Pat. 1901). See 37 CFR 1.75, MPEP § 608.01(i) and § 1302.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,218,366.

Claim 1 is drawn to methods of improving cardiovascular function in a patient with congestive heart failure consisting of the chronic administration of 2-10 g D-ribose 1-4 times/day. Claim 2 provides the addition of additional vasodilator. Claim 3 limits the vasodilator to various agents. Claim 6 is drawn to a method of relieving the symptoms of peripheral vascular disease consisting of administering 2-10 g D-ribose 1-4 times/day for at least 1 week.

Both applications are drawn to methods of treating vascular conditions using the same therapy, i.e. with ribose or ribose and a vasodilator. It is noted that the instant claims are drawn to methods of improving cardiovascular function in a subject with congestive heart failure and the '366 patent is drawn to methods of increasing the tolerance of a mammal to hypoxia. However, hypoxia is seen to be a precipitating factor of congestive heart failure, as evidenced by the attached "How Congestive Heart Failure Works", and as such, it is believed that a skilled

artisan would find it obvious to practice the method of the '366 patent in a patient with congestive heart failure (CHF) as hypoxia is known to occur in vascular disease and known to be a precipitating factor associated with CHF. Claim 10 of the '366 patent further states that hypoxia is due to cardiovascular disease, further overlapping the instant claims of treating CHF with the '366 patent. Moreover, it is noted that the instant application is drawn to using compositions comprising 2-10 grams of ribose one to four times daily and the '366 patent teaches that the dosage administered is to be 1-60 grams (see claim 3). It is well within the purview of a skilled artisan to optimize art known methods to determine optimal dosages for therapeutics.

Claims 1-3 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Omran et al., in view of St. Cyr et al. (US 6,218,366).

Omran et al. teach that ribose improves myocardial function and quality of life in congestive heart failure patients (see title). Omran teach administering 15 g/day of ribose to alleviate problems associated with CHF. What is not taught is to administer an additional vasodilator, nor to administer 2-10g 1-4 times a day.

St. Cyr et al. teach to administer ribose and an additional vasodilator in patients to increase the tolerance to hypoxia.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Omran and St. Cyr to produce the instant invention with these references before them. Absent unexpected results, one of ordinary skill in the art would have a reasonable expectation of success in determining the optimum dosages, as the art teaches

administering 15 grams/day and the instant application teaches a broader range of 2-10g 1-4 times/day, thus encompasses administering 15g/day. As set forth supra, hypoxia is known to be associated with CHF and can occur as a result of CHF. One would be motivated to use ribose as claimed as Omran et al even state that with the known difficulty in managing many CHF patients, ribose should be strongly considered as a therapeutic option in this heart disease state.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. McIntosh III
June 7, 2006
Art Unit 1623